NIAMS Data and Safety Monitoring (DSM) Report Template for Single Site Studies

-Closed Session-

DSM Report Template: Instruction Sheet

The following report template is intended to act as guidance and a reference document for investigators, study staff, data managers, study statisticians and others involved in submitting periodic reports to a Monitoring Body (e.g., Data and Safety Monitoring Board, Safety Officer). The proposed structure should be customized according to the individual study needs. Additional or fewer reports may be appropriate, but the template serves as a starting point.

Prior to the first Monitoring Body report, study team members should review this template and customize it to the specific needs of the protocol. During the introductory call, the designated study team member who is responsible for preparing these reports (i.e., statistician, data manager) should present the customized table shells to the NIAMS and the Monitoring Body. The final format of the reports, tables, and listings will be approved by the Monitoring Body and the NIAMS. This process will ensure the appropriate study data are presented to the Monitoring Body and will promote efficiency in the creation of future safety reports.

The design, scope and nature of a study will impact how data are presented. Outlined below are a few issues that should be considered as this document is tailored:

- For studies in which there are masked treatment groups, the Monitoring Body, at its discretion, may request and review unmasked data in the closed session materials. The decision to present results in an unmasked fashion should be discussed with the NIAMS and the Monitoring Body.

- It is recommended that data stratified by treatment group be masked (i.e., Treatment A versus Treatment B).

- As a general rule, interim results should not be presented unless interim analyses are described in the protocol or the Monitoring Body has requested an interim analysis to assess a safety concern or study futility. The decision whether or not to present interim or final results in this report should be discussed with the Monitoring Body and the NIAMS.

Template Recommendations:

- In the following templates, the instructions, explanatory text, and examples are indicated by blue text. Be sure to replace examples with protocol-specific details.
- Instructional text will also be enclosed in {braces} to signify this text for screen-readers used by the visually impaired.
- Delete template-specific instructional text and this Instruction Sheet during the report development process.

Report Cover Page

Protocol Title/number:	<Insert title of the protocol>
Grant Number:	<Insert grant number>
Principal Investigator (PI):	<Name of PI PI's Title Institution Address>
Meeting date:	<Insert date of the scheduled meeting, if applicable>
Date of Report:	<Insert date that the report is being issued>
Data as of:	<Insert the date of the data snapshot for the analyses in this report>
Prepared by:	<Name of person who prepared the report Person's Title Place of employment Address>

Table of Contents

Study Administration

Recruitment and Participant Status:

Figures and Tables

Table 1: Participant Enrollment Status by Masked Treatment Group

Data as of: _____

Date of report: _____

	Masked Treatment Group____ (n=)		Masked Treatment Group____ (n=)		Total	
	n	**%***			**n**	**%***
Enrolled		100				100
Active						
Completed Protocol						
	n	**%****			**n**	**%****
Discontinued Treatment/Follow-up Ongoing		100				100
Reason 1 ****						
Reason 2						
	n	**%*****			**n**	**%*****
Discontinued from Treatment/Follow-up Completed		100				100
Reason 1						
Reason 2						
	n	**%*****			**n**	**%*****
Discontinued from Study/Follow-up Not Ongoing		100				100
Reason 1						
Reason 2						

For some protocols, it is important to distinguish between participants who withdrew early from the study and those who discontinued treatment but may or may not still be followed.

***** % of participants who are enrolled.** ****** % of participants who have discontinued treatment, but continued to be followed as part of the study.*
******* % of participants who have discontinued the study and are no longer being followed. ******** Reasons should be customized with items relevant to the study protocol.*

Table 2: Demographics by Masked Treatment Group

Data as of: _____

Date of report: _____

		Masked Treatment Group____ (n=)		Masked Treatment Group____ (n=)		Total
Characteristics*		n	(%)	n	(%)	n (%)
Total Enrolled:						
Gender	Male					
	Female					
Ethnicity	Hispanic or Latino					
	Not Hispanic or Latino					
	Missing					
Race	American Indian/Alaska Native					
	Asian					
	Black or African American					
	Native Hawaiian or Other Pacific Islander					
	White					
	More than one race					
	Missing					
Education	Grade School					
	High School or equivalent					
	Some college, no degree					
	College degree					
	Graduate degree					
	Doctoral					
Age	Mean					
	Standard Deviation					
	Median					
	Minimum					
	Maximum					

***** *Characteristics should be customized with items relevant to the study protocol; the items listed are only examples.*

Table 3: Key Baseline Characteristics by Masked Treatment Group

Data as of: _____

Date of report: _____

Characteristics*		Masked Treatment Group ____ (n=____)	Masked Treatment Group ____ (n=____)
		TOTAL	TOTAL
		n (%)	n (%)
Body Mass Index	Below 18.5		
	18.5 – 24.9		
	25.0 – 29.9		
	30.0 and Above		
Western Ontario and McMaster Universities Arthritis Index (WOMAC) Total Score	Mean		
	Standard Deviation		
	Median		
	Minimum		
	Maximum		

***** *Characteristics should be customized with items relevant to the study protocol (e.g., stratification variables); the items listed are only examples.*

Table 4: Study Duration for All Participants by Masked Treatment Group

Data as of: _____

Date of report: _____

	Masked Treatment Group ____ (n=____)		Masked Treatment Group ____ (n=____)	
Time in Study*	**Expected****	**Actual*****	**Expected****	**Actual*****
Total n=	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Visit 1				
Visit 2				
Visit 3				
Visit 4				
Completed Study				

** Should be customized to visit schedule and can be shown by visits, days, weeks, months, or treatment periods.*

*** Number of participants expected to complete each study milestone.*

**** Number of participants who completed each study milestone.*

Study Administration

Data Quality Table

Table 5: Summary of Missed Visits by Masked Treatment Group

Data as of: _____

Date of report: _____

	Masked Treatment Group ____ (n=____)	**Masked Treatment Group ____ (n=____)**
	Total	**Total**
Missed Visits	**n (%)**	**n (%)**
Number of Completed Participants		
Number of Participants Missing Visits		
Number of Missed Visits		
Average Number of Missed Visits for Completed Participants		
Number of Active Participants		
Number of Participants Missing Visits		
Number of Missed Visits		
Average Number of Missed Visits for Active Participants		

{This table should display the number of participants missing visits and the number of actual missed visits divided by those who are currently active on the protocol and those who completed.}

Safety Assessments for All Participants:

Tables and Listings

Table 6: Incidence of Adverse Events by Body System and Preferred Term and Masked Treatment Group

Data as of: _____

Date of report: _____

	Masked Treatment Group ____ (n=____)			Masked Treatment Group ____ (n=____)		
Body System and Preferred Term*	**Total n=**			**Total n=**		
	n**	**(%)*****	**Events********	**n****	**(%)*****	**Events********
Overall						
Body System 1********						
Preferred Term 1						
Preferred Term 2						
etc.						
Body System 2						
Preferred Term 1						
Preferred Term 2						
etc.						
Body System 3						
etc.						

{Standard medical terminology should be used when recording AEs. Furthermore, it is recommended that studies that plan to submit data to regulatory authorities should code their AE data using an electronic coding system such as the Medical Dictionary for Regulatory Activities (MedDRA) or the Common Terminology Criteria for Adverse Events (CTCAE).

**The Preferred Term is a distinct descriptor (single medical concept) for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical, or medical procedure, and medical, social, or family history characteristics.*

*** Number of participants experiencing an AE (participant is to be counted only once for each adverse event).*
**** % of total number of participants in the study.*

***** Number of events for Body System and Preferred Term.*

****** Body Systems may include: Blood and lymphatic system disorders; Cardiac disorders; Congenital, familial and genetic disorders; Ear and labyrinth disorders; Endocrine disorders; Eye disorders; Gastrointestinal disorders; General disorders and administration site conditions; Hepatobiliary disorders; Immune system disorders; Infections and infestations; Injury, poisoning and procedural complications; Investigations; Metabolism and nutrition disorders; Musculoskeletal and connective tissue disorders; Neoplasms benign, malignant and unspecified (incl cysts and polyps); Nervous system disorders; Pregnancy, puerperium and perinatal conditions; Psychiatric disorders; Renal and urinary disorders; Reproductive system and breast disorders; Respiratory, thoracic and mediastinal disorders; Skin and subcutaneous tissue disorders; Social circumstances; Surgical and medical procedures; Vascular disorders.*

Table 7: Severity of Adverse Events by Preferred Term and Masked Treatment Group

Data as of: _____

Date of report: _____

Preferred Term*	Masked Treatment Group ____ Total n=			Masked Treatment Group ____ Total n=		
	Mild	Moderate	Severe	Mild	Moderate	Severe
	n** (%)***	n (%)	n (%)	n** (%)***	n (%)	n (%)
Preferred Term 1						
Preferred Term 2						

**For each preferred term, sort by most common event in descending order of incidence.*

***Number of participants experiencing a certain severity of an adverse event where each participant is counted only once at highest level of severity.*

****% of participants experiencing a certain severity of an adverse event.*

Listing 1: Adverse Events by Masked Treatment Group

Data as of: _____

Date of report: _____

Participant ID	Masked Treatment Group	Age	Gender	Event Term	AE Onset Date	AE Stop Date	Study Intervention Start Date	Study Intervention Stop Date	Relationship*	Participant discontinued from intervention?	Expected (Y/N)	Severity**	Outcome***	Serious (Y/N)

***** *Relationship should be specifically defined for each study (i.e., Relationship to intervention, Relationship to study drug, etc.) The following are commonly used categories: Definitely, Probably/Possibly, Not Related*

****** *The following are commonly used categories: Mild, Moderate, Severe.*
******* *Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present-no treatment
Residual effect(s) present-being treated
Subject died

Listing 2: Serious Adverse Events by Masked Treatment Group*

Data as of: _____

Date of report: _____

Participant ID	Masked Treatment Group	Age	Gender	Event Term	Study Intervention Duration**	Study Intervention Start Date	Study Intervention Stop Date	SAE Onset Date	SAE Stop Date or Ongoing	Relationship to Study***	Expected? (Yes/No)	Outcome ****	Unanticipated Problem?***** (y/n)

** This listing can be sorted by SAE Description or by Participant ID.*
*** The number of days on study treatment at the onset of the SAE.*
**** Relationship should be specifically defined for each study (i.e., Relationship to intervention, Relationship to study drug, etc.) The following are commonly used categories: Definitely, Probably/Possibly, Not Related.*
***** Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present-no treatment
Residual effect(s) present-being treated
Subject died

******The incident must meet the following criteria to qualify as an Unanticipated Problem:*

- *was unexpected in terms of nature, severity, or frequency*
- *is definitely or possibly related to participation in the research*
- *suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized*

NOTE: All AEs in Listing 1 that have been designated as an SAE ("Y") should be also listed on this Listing.

Listing 3: Deaths by Masked Treatment Group

Data as of: _____

Date of report: _____

Participant ID*	Masked Treatment Group	Gender	Age	Date Enrolled	Date of Death	Study Intervention Start Date	Study Intervention Stop Date	Cause of Death	Relationship **

***** *It is expected that individuals will be listed on Listing 1: Adverse Events, Listing 2: Serious Adverse Events and the more detailed Listing 3: Deaths by Site.*

****** *The following are commonly used categories for relationship: Definitely, Probably/Possibly, Not Related.*

Table 8: Laboratory Test Results Summary by Masked Treatment Group*

Data as of: _____

Date of report: _____

Laboratory Test	Masked Treatment Group	Study Visits							----------Change from Baseline----------					
			n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Test 1	___ **(n=)**	Screening												
		Visit 1												
		Visit 2												
	___ **(n=)**	Screening												
		Visit 1												
		Visit 2												
Test 2	___ **(n=)**	Screening												
		Visit 1												
		Visit 2												
	___ **(n=)**	Screening												
		Visit 1												
		Visit 2												
etc…														

** Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results.*

Table 9: Laboratory Test Results Summary by Masked Treatment Group*

Data as of: _____

Date of report: _____

Laboratory Test**	Normal Range	Masked Treatment Group	Study Visits							----------Change from Baseline----------					
				n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Test 1		___ **(n=)**	Screening												
			Visit 1												
			Visit 2												
		___ **(n=)**	Screening												
			Visit 1												
			Visit 2												
Test 2		___ **(n=)**	Screening												
			Visit 1												
			Visit 2												
		___ **(n=)**	Screening												
			Visit 1												
			Visit 2												
etc…															

** One table for each site.*
*** Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results.*

Listing 4: Clinically Significant Abnormal Lab Values by Masked Treatment Group

Data as of: _____

Date of report: _____

Participant ID	Masked Treatment Group	Study Visit	Lab Test	Baseline Result	Current Result	% Change from Baseline	Normal Range

{Lab tests that are deemed clinically significant as specified in the study protocol should be listed along with baseline result and normal range as stated by the study lab.}

Listing 5: Unanticipated Problems by Masked Treatment Group

Data as of: _____

Date of report: _____

Date UP Identified	Date of UP incident	UP Description*	Subject ID (or describe group affected)	Masked Treatment Group (if applicable)**	Action taken*** (1 -10, include all that apply)	Action taken, specify	SAE? (yes/no)	Reported to the IRB? (yes/no)	IRB action required? If yes, describe response from IRB (attach correspondence, if necessary)

{The incident must meet the following criteria to qualify as an Unanticipated Problem:

- *was unexpected in terms of nature, severity, or frequency*
- *is definitely or possibly related to participation in the research*
- *suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized}*

**Describe harm or potential harm that occurred to subject(s), whether the incident is resolved, and whether the subject(s) remains in the study. If the Unanticipated Problem is a serious adverse event, submit this form and complete the Serious Adverse Event form.*

***If the Unanticipated Problem affects a particular group in the study, please identify that group, i.e., subjects in Treatment Group A, subjects enrolled before January 1, 2014, etc. If a group of individuals affected is across more than one treatment group, it may not be possible to complete this field.*

****Action taken with the study as a result of the Unanticipated Problem? (include all that apply)*

1- No action
2- Revise protocol to eliminate apparent immediate hazards to subjects
3 - Modification of inclusion or exclusion criteria to mitigate newly identified risks
4 - Implementation of additional procedures for monitoring subjects
5 - Suspension of enrollment of new subjects
6 - Notify currently enrolled subjects
7- Suspension of research procedures in currently enrolled subjects
8 - Modification of consent documents to include a description of newly recognized risks (site and/or study wide)
9 - Provision of additional information about newly recognized risks to previously enrolled subjects
10 – Other, specify

Listing 6: Protocol Deviations by Masked Treatment Group

Data as of: _____

Date of report: _____

Participant ID	Masked Treatment Group	Deviation Date	Deviation Description*	Deviation Category**

***Deviation Description - record what occurred and why. For example, an expired drug was used by a new coordinator who did not check the expiration date. The description should also include remedies taken. In this case, the participant/subject was called to return the drug and was issued unexpired medication.*

****Deviation Category – provide a category of the protocol deviation description. Example deviation categories include: Randomization of ineligible participant; Failure to obtain consent; Participant seen outside window of follow-up; Not reporting serious adverse event.*